inpatient rehabilitation facility prospective payment system for cost reporting periods beginning on or after January 1, 2002. *Form Number:* CMS–10036 (OMB# 0938–0842); *Frequency:* Annually; *Affected Public:* Business or other for-profit, Not-for-profit institutions, State, Local or Tribal Governments and Federal Government; *Number of Respondents:* 1202; *Total Annual Responses:* 396,660; *Total Annual Hours:* 337,161.

2. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* New Freedom Initiative—Web-based Reporting System for Grantees; *Use:* CMS currently awards competitive grants to States and other eligible entities for the purpose of designing and implementing effective and enduring improvements in community-based long-term services and support systems. CMS currently requires grantees to report on a quarterly, semi-annual, and or annual basis depending upon the grant type. CMS requires the information obtained through web-based grantee reporting for two reasons: (1) In order to effectively monitor the grants; and, (2) To report to Congress and other interested stakeholders the progress and obstacles experienced by the grantees. The grantees are the respondents to the web-based reporting system. *Form Number:* CMS–10161 (OMB# 0938–0979); *Frequency:* annually, semi-annually, and quarterly; *Affected Public:* State, Local or Tribal Governments; *Number of Respondents:* 171; *Total Annual Responses:* 428; *Total Annual Hours:* 3,764.

3. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Request for Certification as a Supplier of Portable X-ray Services and Portable X-ray Survey Report Form under the Medicare/Medicaid Program and Supporting Regulations in 42 CFR 486.100–486.110; *Use:* The Medicare program requires portable X-ray suppliers to be surveyed for health and safety standards. The CMS–1882 is the survey form that records survey results. The CMS–1880 is used by the surveyor to determine if a portable X-ray applicant meets the eligibility requirements. *Form Numbers:* CMS–1880/1882 (OMB# 0938–0027); *Frequency:* Occasionally; *Affected Public:* State, Local or Tribal Governments; *Number of Respondents:* 544; *Total Annual Responses:* 68; *Total Annual Hours:* 4,760.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS' Web site at *http://www.cms.hhs.gov/PaperworkReductionActof1995,* or E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov,* or call the Reports Clearance Office on (410) 786–1326.

In commenting on the proposed information collections please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in one of the following ways by *December 23, 2008:*

1. *Electronically.* You may submit your comments electronically to *http://www.regulations.gov.* Follow the instructions for ''Comment or Submission'' or ''More Search Options'' to find the information collection document(s) accepting comments.

2. *By regular mail.* You may mail written comments to the following address:

CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, *Attention:* Document Identifier/OMB Control Number_____, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: October 16, 2008.

Michelle Shortt,

Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. E8–25206 Filed 10–23–08; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–2896–FN]

Medicare and Medicaid Programs; Conditional Approval of the Joint Commission's Continued Deeming Authority for Critical Access Hospitals

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Conditional Notice of Approval.

SUMMARY: This notice announces our decision to conditionally approve, with a probationary period, the Joint Commission's request for continued recognition as a national accreditation program for critical access hospitals (CAHs) seeking to participate in the Medicare or Medicaid programs.

DATES: *Effective Date:* This conditional notice of approval is effective November 21, 2008 through November 21, 2011, with a 180-day probationary period through May 20, 2009.

FOR FURTHER INFORMATION CONTACT: Cindy Melanson, (410) 786–0310, Patricia Chmielewski (410) 786–6899.

SUPPLEMENTARY INFORMATION:

I. Background

Under the Medicare program, eligible beneficiaries may receive covered services in a CAH provided certain requirements are met. Sections 1820(c)(2)(B) and 1861(mm) of the Social Security Act (the Act) establish distinct criteria for facilities seeking designation as a CAH. Under this authority, the minimum requirements that a CAH must meet to participate in Medicare are set forth in regulations at 42 CFR part 485, subpart F (Conditions of Participation: Critical Access Hospitals (CAHs)) which determine the basis and scope of CAH covered services. Conditions for Medicare payment for CAHs can be found at 42 CFR 413.70. Applicable regulations concerning provider agreements are at 42 CFR part 489 (Provider Agreements and Supplier Approval) and those pertaining to facility survey and certification are at part 488, subparts A and B.

A. Verifying Medicare Conditions of Participation

In general, we approve a CAH for participation in the Medicare program if it is participating as a hospital at the time it applies for CAH designation, and it is in compliance with parts 482 (Conditions of Participation for Hospitals) and 485, subpart F (Conditions of Participation: Critical Access Hospital (CAHs)).

For a CAH to enter into a provider agreement, a State survey agency must certify that the CAH is in compliance with the conditions or standards set forth in section 1820 of the Social Security Act and part 485 of our regulations. Thereafter, the CAH is subject to ongoing review by a State survey agency to determine whether it continues to meet the Medicare requirements. There is, however, an alternative to State compliance surveys. Accreditation by a nationally-recognized accreditation program can substitute for ongoing State review.

Section 1865(b)(1) of the Act provides that, if a provider entity demonstrates through accreditation by an approved national accreditation organization that all applicable Medicare conditions are met or exceeded, we may ''deem'' those provider entities as having met the requirements. Accreditation by an

accreditation organization is voluntary and is not required for Medicare participation.

If an accreditation organization is recognized by the Secretary as having standards for accreditation that meet or exceed Medicare requirements, a provider entity accredited by the national accrediting body's approved program may be deemed to meet the Medicare conditions. A national accreditation organization applying for approval of deeming authority under part 488, subpart A must provide us with reasonable assurance that the accreditation organization requires the accredited provider entities to meet requirements that are at least as stringent as the Medicare conditions. Our regulations concerning re-approval of accrediting organizations are set forth at section § 488.4 and § 488.8(d)(3). The regulations at § 488.8(d)(3) require accreditation organizations to reapply for continued approval of deeming authority every six years, or sooner as we determine. The Joint Commission's term of approval as a recognized accreditation program for CAHs expires November 21, 2008.

II. Deeming Applications Approval Process

Section 1865(b)(3)(A) of the Act, recodified under the Medicare Improvements for Patients and Providers Act of 2008 (Pub. L. 110–275, July 15, 2008)(MIPPA) as section 1865(a)(3)(A), provides a statutory timetable to ensure that our review of deeming applications is conducted in a timely manner. The Act provides us with 210 calendar days after the date of receipt of a complete application to conduct our survey activities and application review process. Within 60 days of receiving a complete application, we must publish a notice in the **Federal Register** that identifies the national accreditation body making the request, describes the request, and provides no less than a 30-day public comment period. At the end of the 210-day period, we must publish an approval or denial of the application.

III. Provisions of the Proposed Notice and Response to Comments

On May 23, 2008, we published a proposed notice (73 FR 30107) announcing the Joint Commission's request for re-approval as a deeming organization for CAHs. In the proposed notice, we detailed our evaluation criteria. Under section 1865(b)(2) of the Act (now section 1865(a)(2))and our regulations at § 488.4 (Application and reapplication procedures for accreditation organizations), we conducted a review of the Joint Commission application in accordance with the criteria specified by our regulation, which include, but are not limited to the following:

- An onsite administrative review of Joint Commission's (1) Corporate policies; (2) financial and human resources available to accomplish the proposed surveys; (3) procedures for training, monitoring, and evaluation of its surveyors; (4) ability to investigate and respond appropriately to complaints against accredited facilities; and, (5) survey review and decision-making process for accreditation;
- A comparison of the Joint Commission's CAH accreditation standards to our current Medicare CAH conditions for participation; and,
- A documentation review of the Joint Commission's survey processes to:
  - Determine the composition of the survey team, surveyor qualifications, and the ability of the Joint Commission to provide continuing surveyor training;
  - Compare the Joint Commission's processes to those of State survey agencies, including survey frequency, and the ability to investigate and respond appropriately to complaints against accredited facilities;
  - Evaluate the Joint Commission's procedures for monitoring providers or suppliers found to be out of compliance with the Joint Commission program requirements. The monitoring procedures are used only when the Joint Commission identifies noncompliance. If noncompliance is identified through validation reviews, the survey agency monitors corrections as specified at § 488.7(d);
  - Assess the Joint Commission's ability to report deficiencies to the surveyed facilities and respond to the facility's plan of correction in a timely manner;
  - Establish the Joint Commission's ability to provide us with electronic data and reports necessary for effective validation and assessment of the Joint Commission's survey process;
  - Determine the adequacy of staff and other resources;
  - Review the Joint Commission's ability to provide adequate funding for performing required surveys;
  - Confirm the Joint Commission's policies with respect to whether surveys are announced or unannounced; and,
  - Obtain the Joint Commission's agreement to provide us with a copy of the most current accreditation survey together with any other information related to the survey as we may require, including corrective action plans.

In accordance with section 1865(a)(3)(A) of the Act, the May 23, 2008 proposed notice (73 FR 30107) also solicited public comments regarding whether the Joint Commission's requirements met or exceeded the Medicare conditions of participation (CoPs) for CAHs. We received one public comment in response to our proposed notice.

Comment: This commenter expressed serious concerns related to the Joint Commission statutory deeming authority for hospitals set forth in 1865(a) of the Social Security Act. This commenter contends that the Joint Commission's special deeming authority for hospitals has led to a significant decline in hospital quality.

Response: On July 15, 2008, Congress enacted MIPPA. Section 125 of this Act revoked the Joint Commission's previously unique irrevocable statutory deeming authority for hospitals, and includes a 24-month transition period. Effective July 15, 2010, the Secretary may recognize the Joint Commission as a national accreditation body for hospitals based on terms and conditions, and upon submission of such information, as the Secretary may require. In order to be considered for approval as a nationally recognized accreditation program for hospitals, the Joint Commission will have to submit an application in accordance with our requirements at § 488.4, so that we can ensure that their requirements for hospital accreditation meet or exceed those of Medicare's. The Joint Commission's hospital program will be subject to the same initial and periodic CMS review as all other accreditation organization's deemed programs. However, we note that the Joint Commission has always been required by section 1865(b) of the Act (now section 1865(a)) to apply for deeming authority for CAHs, subject to the same terms and conditions as all other national accrediting organizations. Consequently, we note that the commenter's observations are not directly related to this application for continued deeming authority for CAHs. The Joint Commission last was granted recognition as an approved accreditation organization for CAHs for a six year term effective November 21, 2002 (67 FR 54657, August 23, 2002).

IV. Provisions of the Final Notice

A. Differences Between the Joint Commission's Standards and Requirements for Accreditation and Medicare's Conditions and Survey Requirements

We compared the Joint Commission's accreditation requirements and survey process with the Medicare CAH CoPs

and survey process as outlined in the State Operations Manual (SOM). Our review and evaluation of the Joint Commission's deeming application, which were conducted as described in section III of this final notice, yielded the following:

- The Joint Commission amended their policies to eliminate the use of supplemental findings. All survey findings will be identified as a requirement for improvement, and will, therefore, require resolution through the evidence of standards compliance process;
- The Joint Commission modified its evidence of standards compliance process (ESC) to ensure that accepted ESCs contain the critical information necessary to provide assurance that an identified deficiency had been adequately corrected;
- The Joint Commission modified its survey report to clearly identify whether an identified deficient practice represented condition-level noncompliance or standard-level noncompliance;
- The Joint Commission developed and conducted training on the CMS documentation requirements for its surveyors to ensure that issues cited would provide a clear and detailed description of the deficient practice and relevant finding;
- The Joint Commission modified its policies regarding complaint investigation activities to comply with the requirements at § 488.4(a)(6) and chapter five of the SOM;
- To meet the Medicare requirements related to unannounced surveys at 2700A of the SOM, the Joint Commission modified its electronic application process to no longer allow the CAH to indicate ''avoid dates'' or ''a ready month'' in which organizations could receive an accreditation survey for deemed status;
- The Joint Commission revised its accreditation decision letters to ensure they are accurate and contain all the required elements necessary for the CMS Regional Office to render a decision regarding deemed status of a CAH;
- The Joint Commission modified its policies regarding condition-level noncompliance identified during an initial certification survey for participation in Medicare in accordance with section 2005A of the SOM;
- The Joint Commission added language to its standards, and interpretive guidance to address the requirements at § 485.610(e) (off-campus and co-location requirements) and § 485.635(e) (rehabilitation therapy services);
- To meet the Medicare requirements at § 485.616(a) (agreements with network hospitals), the Joint Commission amended its standards to include a requirement for CAHs that are part of a rural health network to have an agreement with at least one hospital;
- To meet the Medicare requirements at § 485.618(c)(2) (blood storage facilities) and § 485.635(c)(4)(i) (contractual and arranged services), the Joint Commission amended its standards to clarify that the governing body must approve all services provided at the CAH through contractual agreements;
- To meet the Medicare requirements at § 485.623(b)(5), the Joint Commission revised several of its elements of performance (EP) to address the ventilation, lighting, and temperature control in pharmaceutical, patient care, and food preparation areas;
- To meet the Medicare requirements at § 485.623(c)(1), the Joint Commission modified its standards and EPs to address training of staff on handling emergencies;
- To meet the Medicare requirements at § 485.623(d)(3), the Joint Commission added language to the appendix of the CAH manual to clarify the provision of waivers related to life safety code (LSC);
- To meet the Medicare requirements at § 485.623(d)(4), the Joint Commission added an EP to address the requirement that the CAH must maintain written evidence of regular inspection and approval by state and local fire control agencies;
- To meet the Medicare requirements at § 485.623(d)(7), the Joint Commission amended its crosswalk to include language related to requirements of alcohol-based hand rubs;
- The Joint Commission added language to its standards to address the requirements at § 485.627(b) (disclosure of ownership and control);
- To meet the Medicare requirements at § 485.635(d)(2), the Joint Commission added language to its standards to address the requirements related to the physician assistants (specifically, supervision and evaluation of nursing care);
- To meet the Medicare requirements at § 485.639(c), the Joint Commission added language to its standards to address who may administer anesthesia;
- To meet the Medicare requirements of § 12.25(e), the Joint Commission added language to the CAH manual that states that CAHs are not permitted to have satellite facilities;
- To meet the Medicare requirements at § 412.27(a), the Joint Commission added language to its standards to include provisions related to admission of psychiatric patients;
- To meet the Medicare requirements at § 412.27(c)(4), the Joint Commission added language to its standards to address the requirements related to progress notes;
- To meet the Medicare requirements at § 412.27(d)(5), the Joint Commission added language to its standards to address the responsibilities of the social work staff;
- To address the requirement that a doctor manage or coordinate a patient's general medical condition at § 482.12(c)(4), the Joint Commission added language to its standards for a distinct part unit(s) (DPU);
- To address the requirements related to budget and capital expenditures at § 482.12(d)(2)–(5), the Joint Commission added language to its standards for DPUs;
- To address the requirements related to the governing body's responsibility to review and resolve grievances at § 482.13(a)(2), the Joint Commission added language to its standards for DPUs;
- To address the requirements of the patient's right to access records at § 482.13(d)(2), the Joint Commission added language to the standards for DPUs;
- To address the requirements related to duties and privileges of the medical staff at § 482.22(c)(2), the Joint Commission added language to its standards for DPUs;
- To address the requirements related to autopsies at § 482.22(d), the Joint Commission added language to its standards for DPUs; and,
- To address the requirements related to the availability of a registered nurse at § 482.23(b), the Joint Commission added language to its standards for DPUs.

Since the Joint Commission's last application for deeming authority for CAHs in 2002, CMS revised the CAH requirements August 11, 2004 (60 FR 49272) to include a new condition at § 485.647. This condition of participation outlines the eligibility requirements for CAHs that wish to have a DPU. Under this condition, a CAH can provide inpatient psychiatric or rehabilitation services in a DPU so long as the services furnished in this DPU comply with the hospital requirements specified at § 482, the requirements for excluded hospital units at § 412.25, and the additional requirements at § 412.27 for excluded psychiatric units; and §§ 412.29 and 412.30 for excluded rehabilitation units.

As a result, the Joint Commission had to address all of the DPU requirements

at § 485.647, including a crosswalk addressing the Medicare hospital CoPs at § 482, as part of its application for renewal of CAH deeming authority. Given the Joint Commission's unique statutory deeming authority for hospitals as set forth in former section 1865(a) of the Act, the Joint Commission had previously not been subject to a comparability review of its hospital accreditation program in accordance with the requirements at §§ 488.4 and 488.8. Review of the Joint Commission revised accreditation standards for hospitals revealed that significant gaps remain between the Joint Commission standards and the Medicare hospital CoPs.

In accordance with § 488.8(d)(3), every six years, or sooner as determined by CMS, an approved accreditation organization must reapply for continued approval of deeming authority. CMS notifies the organization of the materials the organization must submit as part of the reapplication procedure. An accreditation organization that is not meeting the requirements of this subpart, as determined through a comparability review, must furnish CMS, upon request and at any time, with the reapplication materials CMS requests. CMS will establish a deadline by which the materials are to be submitted.

In accordance with § 488.8(f)(3)(i), if we determine that an AO has failed to adopt requirements comparable to CMS requirements, we may grant a conditional approval of the AO's deeming authority for a period of up to 180 days to adopt comparable requirements. Within 60 days after the end of this period, CMS will make a final determination as to whether or not the Joint Commission's CAH accreditation requirements are comparable to CMS requirements and issue an appropriate notice that includes reasons for our determination no later than July 19, 2009. If the Joint Commission has not made improvements acceptable to CMS during this period, CMS may remove recognition of deemed authority for its CAH program effective up to 30 days from the date we provide written notice to the Joint Commission that its CAH deeming authority will be removed. In addition, because of our concern about DPU standards, once the Joint Commission has implemented their revised CAH DPU standards, we will conduct a survey observation at the next available opportunity to validate proper application of the standards.

B. Term of Approval

Based on the review and observations described in section III of this final notice, specifically remaining significant gaps between the Joint Commission hospital standards for DPUs and Medicare hospital CoPs. We have determined that the Joint Commission's accreditation standards for CAH DPUs require further revision and subsequent review. We are confident that with additional time, the Joint Commission will make the necessary revisions to their DPU standards and implement these revised standards to ensure that the Joint Commission's accreditation program for CAH DPUs meets or exceeds the Medicare requirements as stated at § 485. Therefore, we conditionally approve the Joint Commission as a national accreditation organization for CAHs that request participation in the Medicare program, effective November 21, 2008 through November 21, 2011, with a 180 day probationary period through May 20, 2009.

V. Collection of Information Requirements

This document does not impose information collection and recordkeeping requirements. Consequently, it need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 35).

Authority: Section 1865 of the Social Security Act (42 U.S.C. 1395bb)

(Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program; No. 93.773, Medicare—Hospital Insurance Program; and No. 93.774, Medicare—Supplemental Medical Insurance Program)

Dated: September 11, 2008.

Kerry Weems,

Acting Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. E8–25193 Filed 10–23–08; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–3205–PN]

Medicare Program; Application by the American Association of Diabetes Educators (AADE) for Recognition as a National Accreditation Organization for Accrediting Entities To Furnish Outpatient Diabetes Self-Management Training

AGENCY: Centers for Medicare & Medicare Services (CMS), HHS.

ACTION: Proposed notice.

SUMMARY: This proposed notice announces the receipt of an application from the American Association of Diabetes Educators (AADE) for recognition as a national accreditation program for accrediting entities that wish to furnish outpatient diabetes self-management training to Medicare beneficiaries. The statute requires that the Secretary publish a notice identifying the national accreditation body making the request, describing the nature of the request, and providing at least a 30-day public comment period.

DATES: To be assured consideration, comments must be received at one of the addresses provided below no later than 5 p.m. on November 24, 2008.

ADDRESSES: In commenting, please refer to file code CMS–3205–PN. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on specific issues in this regulation to *http://www.regulations.gov*. Follow the instructions under the more search options tab.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, *Attention:* CMS–3205–PN, P.O. Box 8016, Baltimore, MD 21244–8016.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–3205–PN, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.